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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/729,034
Filing Date: December 04, 2000
Appellant(s): PEDERSON et al.

Nancy M. Lambert
For Appellant

EXAMINER'S ANSWER

This is in response to the Amendment and Response filed on June 3, 2009 and the appeal brief filed on February 10, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

Claims 1-11 have been canceled.

Claims 12-49 are pending, rejected, and appealed.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

An amendment after final rejection was filed on June 3, 2009 and has been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct.

NEW GROUND(S) OF REJECTION

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-21 and 37-49 contain a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification does not seem to delineate a "means for identifying"; "means for generating" nor a "means for constructing".

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

(7) Claims Appendix

The copy of the claims in the appendix to the brief is incorrect, due to the subsequent after-final amendment submitted by appellant and entered by the examiner.

A correct copy of the claims appears in the record as submitted by appellant on June 3, 2009.

(8) Evidence Relied Upon

6,157,853	Blume	2-2000
5,562,448	Mushabac	10-1995
6,509,739	Afsah	3-2003
2002/0077865	Sullivan	2-2002
6.662,081	Jacober	2-2004

"Guideline for Prevention of Surgical Site Infection" by Mangram et al; American Journal of Infection Control, 1999, Vol. 27, pp.97-134.

Ormonde-Walshe, Sarah, "Computerized databases in infection control", Nursing Standard, January 2000, Vol. 14, No. 18, pp. 43.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12-21 and 37-49 contain a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The specification does not seem to delineate a “means for identifying”.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of

ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 12-22 and 26-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram et al., 'Guideline for prevention of surgical site infection" (hereinafter Guidelines) in view of Ormond-Walshe, Sarah, "Computerized databases in infection control" (hereinafter Walshe) and in further view of US Patent Number 6,157,853 to Blume and in even further view of US Patent Number 5,562,448 to Mushabac and in even further view of US Patent Application

Publication 2002/0077865 to Sullivan and in even further view of US Patent Number 6,509,730 to Afsah.

(A) As per claim 12-13, Guidelines discloses a method for managing the occurrence or risk of surgical site infection incident to a surgical procedure (Guidelines: pages 100-120), the method comprising:

(a) identifies a plurality of stages (mapping) of operative care associated with the surgical procedure, including at least a preoperative stage, an intra-operative stage, and a postoperative stage (Guidelines: page 98);

(b) identifies one or more points-of-care within each identified stage of operative care associated with the surgical procedure (Guidelines: page 98);

(c) for each point-of-care associated with the surgical procedure, identifies one or a plurality of health care delivery practices associated with a surgical procedure sources of measurable risk of surgical site infection (Guidelines: page 98);

(d) for identified surgical site infection risks, identifying at least one practice for either or both managing or reducing the risks, either individually for each risk or collectively for more than one risk (Guidelines: pages 106-116)

Guidelines do not explicitly disclose that the identified practice or practices associated with the surgical procedure within each point-of-care to provide a set of sequential practices throughout each of the stages of operative care (pages 100-120)

Guidelines does not explicitly disclose

Aligning the practices in a manner that provides a desired management of the overall occurrence or risk of surgical site infection. However, Walshe discloses aligning the practices in a manner that provides a desired management (monitoring) of the overall occurrence or risk of surgical site infection (i.e. establishment of surveillance and control programs was strongly associated with reductions)(page 3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the aforementioned limitation as disclosed by Walshe within Guidelines for the motivation of reducing infection rates (page 3).

Guidelines and Walshe does not explicitly disclose that for each of the compliance indicators, generating a flag when a given health care practice is not in compliance with a rule to align the health care practices to the rule, however, this feature is well known in the art as evidenced by the collective teachings of Blume (Col. 7, Ln. 16-33) in view of Mushabac (Col. 4, Ln. 56-Col. 5, Ln. 2).

Blume teaches providing real-time feedback to surgeons during a surgery but does not teach sending flags if the surgical procedure is not in compliance with a rule, however, this feature is taught by Mushabac. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified Blume with the teachings from Mushabac with the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Guidelines in view of Walshe with the aforementioned teachings from Blume in view of Mushabac the motivation of having a means to inform a

surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

The above mentioned references do not teach the following feature which is taught by Sullivan (Section [0055]):

wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk or surgical site infection are selectable for a given health care facility.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Sullivan with the motivation of having a means of allowing a physician to have immediate recall of difficult to remember historical items, as recited in Sullivan (Section [0055]).

The above mentioned references do not teach the following feature which is taught by Afsah (Col. 6, Ln. 9-20):

wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Afsah with the motivation of having a means of determining a benchmark value, as recited in Afsah (Col. 6, Ln. 9-11).

(B) As per claims 14-21, these claims are substantially similar in scope to claims 12-13 and are rejected on the same basis. The limitations claimed in these claims are taught in Guidelines(Pages 100-120).

(C) As per claims 22 and 36, Guidelines discloses a method for managing risks for surgical site infections incident to a surgical procedure, the method comprising:

evaluating a practice associated with the surgical procedure that poses an infection risk during a stage or the surgical procedure (Guidelines: Page 106-116);

Guidelines does not disclose storing data indicative of the practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedures, however, this feature is taught by Walshe (Walshe: Page 3, Paragraph 1). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the aforementioned limitation as disclosed by Walshe within Guidelines for the motivation of developing an enhanced means of reducing infection rates (page 3).

Guidelines in view of Walshe does not teach a step of identifying via a compliance indicator when the data indicative of the practice associated with a procedure is not in compliance with a rule established for the practice, however, this feature is well known in the art as evidenced by the collective teachings of Blume (Col. 7, Ln. 16-33) in view of Mushabac (Col. 4, Ln. 56-Col. 5, Ln. 2).

Blume teaches providing real-time feedback to surgeons during a surgery but does not teach sending flags if the surgical procedure is not in compliance with a rule and also does not teach generating a report that represents a compilation of measurement data associated with the

surgical procedure, however, this feature is taught by Mushabac. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified Blume with the teachings from Mushabac with the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Guidelines in view of Walshe with the aforementioned teachings from Blume in view of Mushabac the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in Mushabac (Col. 4, Ln. 65-Col. 5, Ln. 2).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Sullivan with the motivation of having a means of allowing a physician to have immediate recall of difficult to remember historical items, as recited in Sullivan (Section [0055]).

The above mentioned references do not teach the following feature which is taught by Afsah (Col. 6, Ln. 9-20):

wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the aforementioned references with the teachings from Afsah with the motivation of having a means of determining a benchmark value, as recited in Afsah (Col. 6, Ln. 9-11).

(D) As per claims 26-33 and 37-49, these claims repeat features previously addressed in the rejection of claims 12-25 and are rejected on the same basis.

(E) As per claims 34 and 35, the combined teachings of Mangram in view of Walshe in view of Blume in view of Mushabac in view of Sullivan and in even further view of Afsah teach that the compliance indicator defines a value within a pre-defined quality scale and that the quality scale ranges from 1 to 10 (Mushabac: Col. 4, Ln. 65-Col. 5, Ln. 2). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the Guidelines reference with these teachings from Mushabac with the motivation of having a means to inform a surgeon if there is a deviation (from a health care practice), as recited in (Mushabac: Col. 4, Ln. 65-Col. 5, Ln. 2).

5. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram in view of Ormond-Walshe in view of Blume in view of Mushabac in view of Sullivan in view of Afsah, as applied to claim 22, above, and in even further view of US Patent Number 6,662,081 to Jacober.

(A) As per claim 23, the Guidelines reference does not teach the following feature which is taught by the Jacober reference:

the step of identifying when the data indicative of the practice is not in compliance with the rule comprises generating a flag for the data (Jacober: Claims 32 and 35). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the Guidelines references with the above mentioned teachings from Jacober with the motivation for having a means of producing an alert when data is not in compliance with a rule.

(B) As per claims 24-25, the Guidelines reference does not teach the following feature which is taught by the Jacober reference:

a step of prompting medical personnel to take further action when the flag is generated (Jacober: Claims 32-35) and the flag is cleared when the further action is taken (Jacober: Claim 34). (Note: In Jacober the medical personnel take further action by sliding the tray of the medication dispenser to remove the medication (Claim 32)).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the Guidelines references with the above mentioned teachings from Jacober with the motivation for having a means of producing an alert when data is not in compliance with a rule.

(10) Response to Argument

(1) In response to applicant's argument that that Mushabac and Blume references are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both the instant application and the Mushabac and the Blume references deal with the problem of generating either flags or alerts when a surgical procedure is not in compliance with a rule established for practice, and as has been set forth above, in the rejection of these claims, proper motivation exists for combining these teachings with those of the Guidelines reference. In

addition, the Office would like to point out that adding the well known elements from the Mushabac and Blume references to the Guidelines reference does not produce any new or unexpected result.

(2) Applicants argue that the cited portions of the Sullivan reference are not supported by its provisional application. However, the teachings of the Sullivan patent application publication which are recited in Figure 23 and Section [0055] of the patent application publication are recited on page 19 of its supporting provisional patent application (60/245,255) on page 19, from lines 13-20. Moreover, the Sullivan reference along with the other prior art references used in the rejection of these claims teach surgical procedures and it is inherent that almost all surgeries involve either the cutting of human tissue or the step of making incisions or openings in human bodies and therefore the risk of surgical site infections from the list of surgeries taught in the prior art is inherent in both Sullivan and the other prior art references used in the rejections of these claims.

(3) Applicants argue that the Afsah reference does not teach "wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery services." However, the Office would like to point out that this feature is taught in Figure 16 of the provisional patent application of the Afsah reference (US Provisional Patent Application Number 60/185,129) . Figure 16 of this application clearly shows that the compliance indicators which measure a quality of the delivery of health care delivery services are quantified.

(4) Applicants argue that the Jacober reference does not teach or suggest the identification of when data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure. However, Jacober teaches this feature (Jacober: Claims 32-35).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

(12) Notice to Appellant – Reply is Required

This examiner's answer contains a new ground of rejection set forth in sections (6) and **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are NOT applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Vivek D Koppikar/ /V. D. K./
Primary Examiner, Art Unit 3600

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/Wynn W. Coggins/

Director, Technology Center 3600

Conferees:

Gerald J. O'Connor /GJOC/
Supervisory Patent Examiner,
Group Art Unit 3686

Vincent A. Millin /vm/
Appeals Practice Specialist
Technology Center 3600